

Notice of Allowability

Application No.

10/677,496

Applicant(s)

BLAKE ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment of August 12, 2005.
2. ☒ The allowed claim(s) is/are 29-34.
3. ☒ The drawings filed on 03 October 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

nd

DETAILED ACTION

1. Claims 29-34 are pending and allowed.
2. In the prior action, the Final Action mailed on April 22, 2005, claims 29-34 were pending and rejected. In the After-Final Response of August 12, 2005, the Applicant amended claim 29. In view of the amendment, and the arguments presented (as indicated below), the application is considered to be in condition for allowance.

Specification

3. **(Prior Objection- Withdrawn)** The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not provide antecedent basis for the presently claimed method of producing pertussis toxin comprising the cultivation of *B. pertussis* both 1) in the presence of a reduced concentration of cysteine, and 2) in the presence of a metal salt such as those identified in claim 29. While the disclosure provides support for either 1) or 2) separately (pages 3-4), and the originally filed claims provide support for the combination of 1) and 2) (see e.g., claims 1, 5, 6, and 11), the description does not provide antecedent basis support for the presently claimed combination of 1) and 2). In view of the amendment of the specification, the objection is withdrawn.

Claim Objections

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4. **(Prior Objection- Withdrawn)** Claim 29 was objected to because of the following informalities: the claim provides a list of alternative members, but does not include a comma separating the last and next to last members. In view of the amendment of the claim, the objection is withdrawn.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **(Prior Rejection- Withdrawn)** Claims 29-34 are rejected under 35 U.S.C. 112, first paragraph, as lacking written description support for the claim limitation “wherein the reduced concentration is no more than 0.05 grams of cysteine per liter.” In view of the amendment of the claims to read on methods wherein the cysteine concentration is between 0.04 and .1 g/l, and the examples in the application showing species falling within this range, the rejection is withdrawn.

7. **(Prior Rejection- Withdrawn)** Claims 29-34 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of enhancing the production of PT by culturing *B. pertussis* in a culture media comprising a reduced concentration of cysteine, does not reasonably provide enablement for methods wherein the culture media is deficient in cysteine. In view of the amendment of the claims providing a lower limit on the amount of cysteine present in the culture media, the rejection is withdrawn.

Double Patenting

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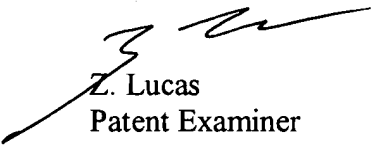
8. **(Prior Rejection- Withdrawn)** Claims 29-34 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,686,180. In view of Applicant's arguments in traversal of the rejection, which are found persuasive, the rejection is withdrawn.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL 8/19/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600